K110551

OCT 2 6 2011

510(K) SUMMARY

A. Submitter Information

DePuy Spine, Inc.
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Raynham, MA 02767

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B. Date Prepared 2/25/2011

C. Device Class Class III

D. Device Name

Trade/Proprietary Name: EXPEDIUM Spine System

Common/Usual Name: Pedicle Screw Spinal System

Classification Name: Spinal interlaminar fixation orthosis per 21 CFR §888.3050

Spinal intervertebral body fixation orthosis per 21 CFR §888.3060

Pedicle screw spinal fixation per 21 CFR §888.3070

Classification Panel: Orthopaedics

FDA Panel Number: 87

E. Product Code(s) NKB, MNI, MNH, KWQ , KWP

F. Predicate Device Name

Trade name: DePuy Spine EXPEDIUM® Spine System (K063772)
DePuy Spine EXPEDIUM® Spine System (K090230)
DePuy Spine EXPEDIUM® Spine System (K092473)
DePuy Spine MOSS MIAMI Spine System (K011182)
DePuy Spine MOSS MIAMI Spine System (K023804)

E. Device Description

The EXPEDIUM® 4.5mm Spine System is a rod-hook-screw system. The EXPEDIUM 4.5mm Spine System proposed single and dual diameter rods are offered in titanium, stainless steel, and cobalt-chromium-molybdenum. They are available in various geometries and sizes to accommodate patient anatomy.

F. Intended Use

The EXPEDIUM Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The EXPEDIUM Spine System metallic components are intended for noncervical pedicle fixation and nonpedicle fixation for fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

The EXPEDIUM PEEK rods are only indicated for fusion procedures for spinal stenosis with instability (no greater than Grade I spondylolisthesis) from L1-S1 in skeletally mature patients.

F. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use

The proposed modifications to the DePuy Spine EXPEDIUM® 4.5mm Spine System are identical to the predicate devices except that the dual diameter rods are offered in cobalt-chromium-molybdenum alloy and in additional sizes. Also, the labeling limitation indicating the minimum screw diameter size no longer applies and is removed from the instructions for use. The design, materials, and technology remain identical to the predicate systems.

G. Materials

Manufactured from ASTM F 1537 implant grade cobalt-chromium-molybdenum alloy, ASTM F 138 implant grade stainless steel, and ASTM F 136 implant grade titanium alloy.

H. Performance Data

Performance data per ASTM F 1717 were submitted to characterize the subject EXPEDIUM Spine System components addressed in this notification. Specifically, static and dynamic compression testing as well as static torsion testing were performed.

I. Conclusion

Both the Performance Testing and Substantial Equivalence Justification demonstrate that the device is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 2 6 2011

DePuy Spine, Inc.
% Mr. Frank Jurczak
Sr. Regulatory Affairs Associate
325 Paramount Drive
Raynham, Masschusetts 02767

Re: K110551
Trade/Device Name: EXPEDIUM Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP, KWQ
Dated: September 30, 2011
Received: October 03, 2011

Dear Mr. Jurczak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110551

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: EXPEDIUM® Spine System

Indications For Use:

The EXPEDIUM Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The EXPEDIUM Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion in skeletally mature patients.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___ ___

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical Orthopedic,
and Restorative Devices

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